

IN THE CLAIMS:

1. (Currently Amended) A dose setting device for use in combination with a fluid-filled reservoir, the dose setting device being adapted for repetitive injection of individual set doses of fluid from the reservoir, the dose setting device comprising:

a housing;

a drive member adapted to expel a dose of fluid from the reservoir;

a spring means for driving the drive member to expel the dose;

~~a dose setting assembly mounted in the housing and connected to the spring means, the dose setting assembly comprising~~ a dose setting assembly mounted in the housing and connected to the spring, the dose setting assembly comprising a first portion being moveable by a user in a first direction to set a selected dose against the bias of the spring means and a remaining portion, wherein movement of the first portion is accompanied by a straining of the spring, and wherein the first portion is moveable in a second direction to selectively adjust the set dose without moving the drive member and wherein the first portion is in continuous engagement with the remaining portion of the dose setting assembly ;

~~a dose setting member being moveable in a first direction to set a selected dose against the bias of the spring means, wherein movement of the dose setting member is accompanied by a straining of the spring, and wherein the dose setting member is moveable in a second direction to selectively adjust the set dose downward without releasing the tension in the spring and without moving the drive member, [whereby no fluid is expelled from the fluid-filled reservoir when the dose setting device is used in combination therewith];~~

a latch means associated with the housing to retain the apparatus in the set position against the bias of the spring means; and

wherein the latch means is releasable to cause the drive member to expel the set dose from the fluid-filled reservoir when the dose-setting device is used in combination therewith, the force for expelling the set dose being provided by the spring means.

2. (Original) A dose setting device as defined in claim 1, wherein the dose setting assembly further comprises a coupling member (60) in displaceable engagement with the dose setting member, the spring means acting on the coupling member, the coupling member acting on the dose setting member (50).

3. (Original) A dose setting device as defined in claim 2, wherein the dose setting member straining of the spring means.

4. (Original) A dose setting device as defined in claim 3, wherein one of the dose setting member (50) and the coupling member (60) is rotationally mounted on the drive member, the other being arranged in sliding, non-rotational engagement with the drive member.

5. (Original) A dose setting device as defined in claim 4, wherein the dose setting member (50) is rotationally mounted on a threaded portion of the drive member whereby selectively setting a dose results in an axial movement of the dose setting member relative to the drive member, and the coupling member (60) is arranged in sliding, non-rotational engagement with the drive member, the spring means acting on the coupling member in a direction corresponding to the longitudinal axis of the drive member.

6. (Original) A dose setting device as defined in claim 5, wherein the threaded connection between the dose setting member and the drive member is of the non-locking type, and wherein the coupling (54, 62) between the dose set-

ting member and the coupling member allows the dose setting member to be rotated in either direction, yet preventing the spring means to counter rotate the dose setting member.

7. (Previously Presented) A dose setting device as defined in claim 4, wherein the coupling(54,62) is arranged between the cooperating surfaces of the dose setting member (50) and the coupling member (60), the coupling providing a resistance against rotation which is sufficient to prevent the spring means from counter rotating the dose setting member, the resistance being easily overcome by a user rotating the dose setting member in either direction, whereby a user can selectively increase or decrease a dose setting.

8. (Previously Presented) A dose setting device as defined in claim 2, further comprising a non-locking and having a pitch angle whereby axial movement of the drive member is obtain

9. (Original) A dose setting device as defined in claim 1, further comprising a threaded member (20) fixed in the housing and comprising a first internal thread, the drive member being a longitudinal piston drive member (30) having an external thread (31) corresponding to the first

internal thread, the threads being non-locking having a pitch angle whereby axial movement of the piston drive member is obtained by an axial force applied to the piston drive member by the spring means.

10. (Original) A dose setting device as defined in claim 9, wherein the dose setting member (50) comprises a second internal thread (53) , the dose setting member being rotationally mounted on the external thread (31) of the piston drive member, whereby selectively setting a dose results in an axial movement of the dose setting member relative to the piston drive member.

11. (Original) A dose setting device as defined in claim 10, wherein the dose setting assembly further comprises a coupling member (60) arranged in sliding, non-rotational engagement with the piston drive member, the spring means acting on the coupling member in a direction corresponding to the longitudinal axis of the drive member, the coupling member acting on the dose setting member (50).

12. (Original) A dose setting device as defined in claim 11, wherein the dose setting member (50) and the coupling member (60) comprise mutually cooperating surfaces (54,62) providing a coupling therebetween such that rotation of the dose setting member in order to set a dose results in straining of the spring means as the coupling member is driven backwardly.

13. (Original) A dose setting device as defined in claim 12, wherein the threaded connection between the dose setting member and the piston drive member is of the non-locking type, and wherein the coupling (54, 62) between the dose setting member and the coupling member allows the dose setting member to be rotated in either direction, yet preventing the spring means to counter rotate the dose setting member.

14. (Previously Presented) A dose setting device as defined in claims 12, wherein the coupling(54, 62) is arranged between the cooperating surfaces of the dose setting member (50) and the coupling member (60), the coupling providing a resistance against rotation which is sufficiently to prevent the spring means to counter rotate the dose setting member, the resistance being easily overcome by a user rotating the dose setting member in either direction, whereby a user can selectively increase or decrease a dose setting.

15. (Previously Presented) A dose setting device as defined in claim 12, wherein the coupling between the dose setting member and the coupling member is provided by coupling parts having surfaces provided with sector shaped teeth (54,

62) having ramp shaped edges, the surfaces being forced against each other with the ramp shaped edges of the teeth on one surface abutting the ramp shaped edges of the teeth on the other surface, such that when the dose setting member is rotated in either direction, the teeth on the coupling parts will slide with their ramp shaped parts over each other, whereby the dosing member is axially displaced against the force of the spring and will jump back each time a top of the teeth is reached, the pitch of the toothing preferably being chosen so that a jump back takes place each time the dose setting is increased by a given dose unit.

16. (Previously Presented) A dose setting device as defined in claim 12, wherein the coupling is a frictional coupling provided between the cooperating surfaces, the necessary compression force between the surfaces being provided by the spring means acting on the coupling member.

17. (Previously Presented) A dose setting device as defined in claim 12, wherein the coupling can be selectively engaged and disengaged allowing the dose setting member to be rotated in either direction.

18. (Original) A dose setting device as defined in claim 17, wherein the coupling is an one-way ratchet mechanism comprising first and second ratchet members (125, 126) and which can be disengaged by relative axial movement between the first and second ratchet members.

19. (Previously Presented) A dose setting device as defined in claim 1, wherein the latch means (80, 90) acts on the drive member.

20. (Currently Amended) A dose setting device for use in combination with a fluid-filled reservoir, the dose setting device being adapted for repetitive injection of individual set doses of fluid from the reservoir, the dose setting device

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comprising:

a housing;

a drive member adapted to expel a dose of fluid from the reservoir;

a spring ~~means~~ for driving the drive member to expel the dose;

a rotatable dose setting assembly mounted in the housing and connected to the spring ~~means~~, wherein the dose setting assembly comprises a coupling providing a resistance which is sufficient to prevent the spring to counter rotate the dose setting member, the resistance being easily overcome by a user setting the dose setting member in either direction, whereby a user can selectively increase or decrease a dose setting the dose setting assembly comprising a dose setting member coupled to the drive member, the dose setting member being moveable in a first direction from an initial position to a selected set position against the bias of the spring means, wherein movement of the dose setting member is accompanied by straining of the spring direction ~~means~~,

a first latch means associated with the housing to retain the device in a set

position against the bias of the spring means,

the first latch means being releasable to cause the drive member to expel the set dose from the fluid-filled reservoir when the dose-setting device is used in combination therewith, the force for expelling the set dose being provided by the spring means, ~~and~~

~~wherein the coupling is adapted to be selectively disengaged thereby allowing the dose setting member to be moved in a second direction to selectively adjust the set dose downward without moving the drive member, [whereby no fluid is expelled from the fluid-filled reservoir when the dose setting device is used in combination therewith].~~

21. (Original) A dose setting device as defined in claim 20 comprising a

second latch means (119) associated with the housing to retain the dose setting member in its coupled position, the second latch means being releasable to allow the dose setting member to disengage from the driving means (103).

22. (Previously Presented) A dose setting device as defined in claim 20 wherein the spring means (106) is strained torsionally thus providing a rotating force on the dose setting member.

23. (Previously Presented) An injection device for repetitive injection of individually set doses of a fluid from a reservoir, comprising:
a body adapted for receiving a cartridge containing a fluid to be injected, the cartridge defining the reservoir and containing a piston, and
a dose setting device as defined in any of the 5 previous claims, the drive member acting on the piston in order to expel fluid from the cartridge.

24. (Previously Presented) An injection device for repetitive injection of individually set doses of a fluid from a reservoir, comprising:
a body comprising a reservoir containing a fluid to be injected, the reservoir containing a piston, and
a dose setting device as defined in claim 1, the drive member acting on the piston in order to expel fluid from the reservoir.

25. (Currently Amended) A method of infusing a flowable drug into a living subject is provided, comprising the steps of:
providing an injection device for repetitive injection of individually set doses of a drug from a reservoir, the injection device comprising a housing, a

reservoir containing a drug to be injected and having an outlet means therefore, a drive member adapted to expel a dose of drug from the reservoir, a spring member for driving the drive means, a dose setting assembly mounted in the housing and connected to the spring means, the dose setting assembly comprising a dose setting member being moveable in a first direction to a selected set position against the bias of the spring means, wherein movement of the dose setting member is accompanied by straining of the spring and wherein the dose setting member is moveable in a second opposite direction to selectively adjust the set dose, the dose setting member being freely moveable in the opposite direction, a latch means associated with the housing to retain the injection device in the set position against the bias of the spring means, and the latch means being releaseable to cause the drive member to expel the set dose from the reservoir, the force for expelling the set dose being provided by the spring means, the method comprising the further steps of:

establishing a flow connection between the subject and the outlet means;

selecting a dose by operating the dose setting member, and

releasing the latch means thereby causing the spring means to drive the drive means to expel the set dose of the drug from the reservoir.